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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,932	12/18/2001	Bret Berner	3100-0001.20	5481

23980 7590 10/07/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



## UNITED STATES DEPARTMENT OF COMMERCE

## Patent and Trademark Office

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10/024932

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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9/3/04

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6/21/04☒ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-28, 36, 62-73 is/are pending in the application.  
Of the above, claim(s) 24-37, 66-73 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-28, 36 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12/18/01, 4/7/03, 1/29/04
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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Applicant's election without traverse of unilayer tablets in Paper No. 6/21/04 is acknowledged.

The disclosure is objected to because of the following informalities: The first sentence in the spec should indicate that the cited application is abandoned.

Appropriate correction is required.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28, 36, 62-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (US Patent No. 6,120,803).

Wong et al. teach a prolonged release active agent dosage form adapted for gastric retention in the stomach (title and abstract) comprising:

Polyethylene oxide, (column 6 line 1) and Ciprofloxacin as an active drug (column 19, line 24).

A polyethylene oxide molecular weight of 50,000 to 10 million is disclosed (column 10, lines 2-3); Polyox® WSR-N-60K is specified (column 26, lines 21-22).

60% active is disclosed (column 22, preparation 1).

Tablets are specified (column 23, line 3)

As to the claimed properties, they must be possessed by the anticipatory composition because it is the same as those claimed.

Applicants in the paper filed 1/29/04 argue a structure implied by process steps, however, no structure is implied by applicants' step. Applicants argue but do not

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exclude the structure limitations in Wong et al. Applicants stipulate "increasing the volume fraction of drug and selecting a polymer that will erode faster than it will swell" (page 11 second full paragraph under "Remarks"). Applicants disclose (page 21 line 13) the same polymer as cited <sup>ab</sup> move in Wong et al as a preferred polymer as well as preferred a drug load of 60-80% (page 37 lines 3-4). Wong et al disclose a range of 50%-80% (column 6 lines 36-40). Thus, Wong et al reads on applicants' stipulated requirements for the claimed release properties.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Webman/LR  
September 8, 2004

EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500